United States District Court
District of Massachusetts

AMPHASTAR PHARMACEUTICALS, INC. and INTERNATIONAL MEDICATION SYSTEMS, LTD.,	)	
Plaintiffs,	)	
v.	)	**Civil Action No. 16-10112-NMG**
MOMENTA PHARMACEUTICALS, INC. and SANDOZ INC.,	)	
Defendants.	)	

MEMORANDUM & ORDER

GORTON, J.

This is an antitrust case in which plaintiffs Amphastar Pharmaceuticals, Inc. ("Amphastar Pharmaceuticals") and International Medication Systems, Ltd. ("IMS")(collectively, "Amphastar" or "plaintiffs") allege that defendants Momenta Pharmaceuticals, Inc. ("Momenta Pharmaceuticals") and Sandoz Inc. ("Sandoz")(collectively, "Momenta" or "defendants") restricted trade and prevented competition in the manufacture and sales of generic enoxaparin.

Pending before the Court are Momenta's motion to dismiss the complaint, which will be treated as a motion to dismiss the amended complaint pursuant to the parties' stipulation, and Momenta's request for judicial notice of certain documents. For the following reasons, both motions will be allowed.

I. Background

A. The parties

Plaintiff Amphastar Pharmaceuticals is a pharmaceutical company presumably incorporated and doing business in California. It develops, manufactures and sells pharmaceutical products including generic enoxaparin throughout the United States. Enoxaparin is an anticoagulant used to prevent blood clots.

Plaintiff IMS is a wholly-owned subsidiary of Amphastar Pharmaceuticals with a principal place of business in California. It manufactures the active ingredient in Amphastar's generic enoxaparin.

Defendant Momenta Pharmaceuticals is the assignee of United States Patent No. 7,575,886 ("the '886 patent") which concerns a testing process used in manufacturing enoxaparin. Momenta Pharmaceuticals acts as the contract laboratory for defendant Sandoz and is a Delaware corporation with a principal place of business in Massachusetts.

Defendant Sandoz distributes, markets and sells generic enoxaparin products throughout the United States. It is a Colorado corporation with a principal place of business in New Jersey. It allegedly entered into a profit-sharing, contractual relationship with Momenta which rendered it the exclusive licensee of the '886 patent.

B. The alleged conduct

In November, 2003, defendants entered into a Collaboration and License Agreement ("Collaboration Agreement") to develop, market and sell "enoxaparin sodium injection" in the United States. The Collaboration Agreement granted an exclusive license of the '886 patent, which had not yet issued, to Sandoz. Plaintiffs claim that the agreement "heavily" incentivized anti-competitive behavior by requiring Sandoz to make "milestone payments", profit share payments and royalty payments to Momenta Pharmaceuticals conditioned upon defendants remaining the sole source of generic enoxaparin in the United States.

In or before February, 2007, the United States Pharmacopeial Convention ("USP") commenced the process for establishing a drug standard to test enoxaparin products. The USP is a scientific and impartial nonprofit organization which sets uniform standards for the identity, strength, quality and purity of medicines, food ingredients and dietary supplements. USP policy prohibits it from favoring one manufacturer over another during the standard-setting process and requires its committee members to disclose any conflicts of interest to the organization. A member with a conflict cannot attend the final discussion, deliberation or vote on the conflicted issues.

Sanofi-Aventis ("Aventis") proposed the standard known as USP Method <207> ("the 207 Method") to the USP. Dr. Zachary

Shriver ("Dr. Shriver"), an employee and director of Momenta Pharmaceuticals who would later be named as an inventor on the '886 patent, served as Momenta's representative on the USP panel tasked with developing and approving the USP standard for enoxaparin. Sandoz also participated in the panel discussions.

The amended complaint alleges that Dr. Shriver and defendants learned, during the USP's consideration of the 207 Method, that Aventis had a pending patent application containing claims which would read on the 207 Method. Defendants purportedly demanded that Aventis abandon its patent application so that any member of the public could practice the enoxaparin standard adopted by the USP. Plaintiffs proffer that demand as evidence that defendants were "very familiar" with the 207 Method and the USP policy on conflicts of interest.

In November, 2008, the USP convened a panel meeting which commenced with a review of the USP policy on conflicts. Momenta Pharmaceuticals presented the 207 Method in a "detailed" presentation to the USP. USP staff reported that it was "not aware of any patent issue that may cover the test". Plaintiffs allege that neither defendants nor Dr. Shriver, who was present at the meeting, disclosed to the USP the conflicts posed by their own pending application for the '886 patent and the Collaboration Agreement. Plaintiffs assert that no other USP

panel member knew that the '886 patent, which eventually issued in August, 2009, would cover the use of the 207 Method.

In December, 2009, the USP approved and adopted the 207 Method as its enoxaparin standard after Aventis agreed to abandon its patent application. The USP convened two more panel meetings in March and April of 2011. Plaintiffs claim that Dr. Shriver and another Momenta representative participated in the meetings and continued to violate their duty to disclose their and defendants' conflicts to the USP.

Sandoz was the first entity to receive approval from the United States Food and Drug Administration ("FDA") to sell generic enoxaparin in the United States in July, 2010. Defendants thus became the sole source of generic enoxaparin until Amphastar also received FDA approval to sell generic enoxaparin in September, 2011. Plaintiffs allege that 1) the FDA required them to comply with the 207 Method as a condition of approval, 2) the 207 Method included steps protected by the patented method, 3) the '886 patent excluded unlicensed competitors from receiving FDA approval and thus 4) the '886 patent excluded new entrants from the market.

Two days after Amphastar received FDA approval, Momenta commenced an action in this Court alleging that Amphastar infringed the '886 patent. Amphastar claims that the lawsuit

prevented it from selling generic enoxaparin in the relevant market.

C. Procedural history

Amphastar initiated this antitrust action by filing a complaint in the Central District of California in September, 2015. The complaint alleges violations of 1) federal antitrust law, i.e., the Sherman Act, 2) California antitrust law, i.e., the Cartwright Act and 3) California state law on unfair business practices. Amphastar amended the complaint in December, 2015 to replace "Sandoz, Pharmaceuticals, Inc." with "Sandoz Inc." as a named defendant.

The amended complaint asserts that Momenta engaged in anti-competitive conduct by executing the Collaboration Agreement, failing to disclose conflicts to the USP and commencing a patent infringement suit against Amphastar for using the 207 Method selected by the USP and required by the FDA. The amended complaint alleges that the anti-competitive conduct kept the price of generic enoxaparin artificially high which cost consumers "billions of dollars in overcharges".

Under Amphastar's theory of antitrust liability, 1) the relevant product market is defined as the United States market for generic enoxaparin or, alternatively, enoxaparin, 2) generic entry into the market results in substantial reductions in price, 3) price-sensitive consumers of generic enoxaparin treat

different brands of generic enoxaparin as reasonable substitutes and 4) generic manufacturers consider the prices set by other generic manufacturers as directly affecting their own prices.

In December, 2015, Momenta filed a motion to dismiss this action and a separate motion to transfer it from the Central District of California to the District of Massachusetts based upon the "substantial overlap" of issues, claims, witnesses and evidence between the instant case and the prior patent case pending in this Court. The California court allowed the motion to transfer. The case was transferred to the District of Massachusetts and assigned to this Session in January, 2016 but Amphastar filed a writ of mandamus to the Ninth Circuit Court of Appeals ("the Ninth Circuit") to appeal that transfer on personal jurisdictional grounds. That petition was denied in May, 2016.

II. Momenta's request for judicial notice

Federal Rule of Evidence 201(b) provides that a court

> may judicially notice a fact that is not subject to reasonable dispute because it: (1) is generally known within the trial court's territorial jurisdiction; or (2) can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned.

The court must take judicial notice if a party requests it to do so and the court is provided with the necessary information. Fed. R. Evid. 201(c).

Here, Momenta requests that the Court take judicial notice of the following eight exhibits:

1) the USP Monograph for Enoxaparin Sodium, dated December 1, 2008,

2) the USP 2009 Revision Bulletin, dated April 29, 2009,

3) the USP General Chapter <207> Test for 1,6-Anhydro Derivative for Enoxaparin Sodium,

4) the USP General Notices and Requirements,

5) Section 420.400 of the FDA Compliance Policy Guides,

6) the transcript of the oral argument held before the Federal Circuit Court of Appeals on May 4, 2015 in Momenta Pharm., Inc. v. Teva Pharm. USA, Inc., 809 F.3d 610 (Fed. Cir. 2015),

7) a supplemental answer which Amphastar filed in the 2011 patent case, Momenta Pharm., Inc. v. Amphastar Pharm., Inc., 11-cv-11681, in response to Momenta's first set of interrogatories, and

8) the slides of a PowerPoint presentation that a Momenta representative made to the USP on November 14, 2008.

Momenta seeks judicial notice of those documents because 1) Exhibits 1, 3 and 8 are incorporated by reference in the amended complaint, 2) Exhibits 1-5 are public records of administrative bodies and 3) Exhibits 6 and 7 are a transcript and pleading from other court proceedings. The Court construes Momenta's request as one to accept the existence of the documents and the statements that they contain but not the substantive truth of such statements.

Amphastar does not challenge the authenticity of any of the listed exhibits but opposes Momenta's request with respect to Exhibit 8 on two grounds. It first asserts that the document does not satisfy the Fed. R. Evid. 201(b)(2) requirement for judicial notice because it

> contains subjective opinions stated by an interested party (namely, Defendants), at a single point in time, which at most highlight factual questions that cannot be resolved on a motion to dismiss.

That concern is misplaced because, as discussed, Momenta simply requests that the Court take judicial notice of the existence of Exhibit 8, not the truth of those statements.

Amphastar next contends that judicial notice is improper because the amended complaint makes "only one reference, in one sentence, to the actual presentation Momenta made on this date" and thus does not incorporate by reference the presentation slides set forth in Exhibit 8.

When faced with a motion to dismiss, courts within the First Circuit Court of Appeals ("the First Circuit") will consider exhibits that were not attached to the complaint if those exhibits are "sufficiently referred to in the complaint". Freeman v. Town of Hudson, 714 F.3d 29, 36 (1st Cir. 2013). Here, however, the mere mention of the November, 2008 presentation in paragraph 40 of the amended complaint does not satisfy that standard. Id. This Court thus declines to construe

the amended complaint as incorporating Exhibit 8 by reference but will, as discussed, take judicial notice of the existence of Exhibit 8 and the statements contained therein.

Accordingly, the Court will take judicial notice of the existence of the eight documents identified in Momenta's request and the statements contained therein.

III. Momenta's motion to dismiss

A. Legal standard

To survive a motion to dismiss under Fed. R. Civ. P. 12(b)(6), a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face. Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007). The court may consider documents incorporated by reference, matters of public record and other matters subject to judicial notice. Giragosian v. Ryan, 547 F.3d 59, 65 (1st Cir. 2008). In assessing the merits of the motion, the court must accept all factual allegations in the complaint as true and draw all reasonable inferences in the plaintiff's favor. Santiago v. Puerto Rico, 655 F.3d 61, 72 (1st Cir. 2011). Threadbare recitals of the legal elements, supported by mere conclusory statements, do not suffice to state a cause of action. Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009).

B. Noerr-Pennington immunity

Momenta seeks to dismiss the federal antitrust claims because, inter alia, the Noerr-Pennington doctrine of antitrust immunity precludes Amphastar from bringing those claims.

The Noerr-Pennington doctrine arises from the principle that Congress intended federal antitrust law to regulate business activity and not political activity. Eastern R. R. Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127, 137 (1961). The immunity doctrine protects valid efforts to elicit favorable government action from antitrust liability even if the ultimate purpose or incidental consequence of the efforts is an anti-competitive restraint on trade. Allied Tube & Conduit Corp. v. Indian Head, Inc., 486 U.S. 492, 499 (1988).

Noerr-Pennington immunity applies when the anti-competitive restraint on trade is the intended "consequence" of government action rather than the "means" of obtaining government action. F.T.C. v. Superior Court Trial Lawyers Ass'n, 493 U.S. 411, 424-25 (1990).

The doctrine, for example, immunizes railroad companies which attempt to influence the legislation and enforcement of anti-trucking laws through a campaign of publicity against their trucker competitors, Noerr, 365 U.S. at 142-44, because the resulting restraint on trade would merely be the consequence of the desired government action. Trial Lawyers, 493 U.S. at 424-

25. The doctrine does not, however, protect defense lawyers who boycott court appointments to represent indigent defendants in order to force a legislative increase in the pay rates of those appointments. Id. at 422-25. That is because the boycott would create an anti-competitive restraint as the means of encouraging favorable legislation. Id. at 425. The boycott would trigger anti-competitive effects regardless of whether it resulted in legislation and thus immunity would not apply. Id.

In short, Noerr-Pennington immunity applies when the anti-competitive restraint on trade results directly from government action and not from private action seeking to elicit government action. Id.

A restraint resulting from private action includes a restraint imposed by a private, standard-setting organization comprising members

> unaccountable to the public and without official [government] authority, many of whom have personal financial interests in restraining competition,

even if the standards selected by the organization are "routinely" adopted by the legislature. Allied Tube, 486 U.S. at 501-02. Under those circumstances, Noerr-Pennington immunity would apply with respect to the anti-competitive effects of the legislative adoption or executive enforcement of those standards but not with respect to the anti-competitive effects of the initial, private selection of the standards. See id. at 500.

Here, Amphastar asserts that Momenta engaged in anti-competitive conduct when it 1) entered into a Collaboration Agreement designating Sandoz as the exclusive licensee of the '886 patent and incentivizing both parties to remain the sole source of generic enoxaparin in the market, 2) did not disclose its conflict of interest to the USP during the USP's selection of the 207 Method and 3) prevented Amphastar from selling generic enoxaparin by commencing a patent infringement suit against Amphastar for using the 207 Method which the FDA required as a condition of selling generic enoxaparin.

The federal antitrust claims in the amended complaint identify the antitrust injuries as the "damaged reputation, reduced financing upon IPO, and lost profits on sales" it suffered as a result of the injunction in the patent infringement case which precluded it from selling generic enoxaparin. The amended complaint identifies no other basis of injury with respect to the federal antitrust claims.

The Court finds that the asserted injuries arise from the FDA's purported adoption of the 207 Method and not from defendants' execution of the Collaboration Agreement or the USP's adoption of the 207 Method. Noerr-Pennington immunity bars Amphastar's federal antitrust claims because they allege injuries which flow from government action. Although the Noerr-Pennington doctrine would not bar antitrust claims for anti-

competitive effects resulting from the Collaboration Agreement or the purported failure to disclose conflicts to the USP, the amended complaint does not claim federal antitrust injuries under those theories of antitrust liability. The amended complaint thus fails to state a federal antitrust claim.

Amphastar suggests in a footnote in its memorandum that Momenta's "misrepresentations [to the USP] fall well within the sham exception" to the Noerr-Pennington doctrine. It cites caselaw which outlines the requirements of the sham exception without specifically alleging how Momenta's purported misconduct meets those requirements. The Court finds its conclusory assertion that the sham exception exempts Momenta's actions from Noerr-Pennington immunity unpersuasive.

The Court declines to address Momenta's other arguments for dismissal because its initial decision is dispositive.

Accordingly, the federal antitrust claims in Counts 1 through 4 of the amended complaint will be dismissed for failure to state a claim.

C. State claims

The amended complaint purports to raise state claims for unfair business practices under Cal. Bus. & Prof. Code § 17200, et seq. and antitrust violations under the Cartwright Act, Cal. Bus. & Prof. Code § 16700, et seq.

Momenta contends that a failure to assert a federal antitrust claim requires dismissal of any claims brought under § 16700 or § 17200 premised on the same set of alleged conduct, see McGlinchy v. Shell Chem. Co., 845 F.2d 802, 811 n.4 (9th Cir. 1988)(§ 16700 claim); LiveUniverse, Inc. v. MySpace, Inc., 304 F. App'x 554, 557-58 (9th Cir. 2008)(§ 17200 claim). Momenta declares that the Court should dismiss the state law claims because it has dismissed the federal antitrust claims.

Amphastar responds tersely that its state law claims survive dismissal for the same reasons that its federal antitrust claims survive dismissal. That assertion is wanting, however, because, as discussed, the federal antitrust claims do not survive dismissal.

Accordingly, Counts 5 and 6 of the amended complaint will also be dismissed.

ORDER

For the foregoing reasons, Momenta's request for judicial notice (Docket No. 18) is **ALLOWED**, and its motion to dismiss (Docket No. 17) is **ALLOWED.**

So ordered.

/s/ Nathaniel M. Gorton
Nathaniel M. Gorton
United States District Judge

Dated July 27, 2016